

AP3 Rec'd PCT/PTO 12 JUN 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: PALLAORO, ET AL.

Serial No. To Be Assigned

Filed: June 12, 2006

For: METHOD FOR IDENTIFYING HISTONE
DEACETYLASE INHIBITORS

Art Unit: _____

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By H. Prowley Date June 12, 2006

10/582621

PATENT Case No. ITR0053YP

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INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: John David Reilly

Attorney For Applicant(s)

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Date: June 12, 2006

10/582621

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

COMPLETE IF KNOWN

Application Number Filing Date First Named Inventor Group Art Unit Examiner Name			
	Pallaoro, et al.		
Attorney Docket Number	ITR0053YP		

Sheet

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of

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Archer, et al., "Histone acetylation and cancer", Curr. Opin. Genet. Devel., Vol. 9, pp. 171-174, 1999.
		Archer, et al., "p21WAF1 is required for butyrate-mediated growth inhibition of human colon cancer cells", PNAS USE, Vol. 95, pp. 6791-6796, June 1998.
		Colletti, et al., "Tryptophan-replacement and indole-modified apicidins: synthesis of potent and selective antiprotozoal agents", Tetrahedron Letters, Vol. 41, pp. 7825-7829, 2000.
		Colletti, et al., "Design and synthesis of histone deacetylase inhibitors: the development of apicidin transition state analogs", Tetrahedron Letters, Vol. 41, pp. 7837-7847, 2000.
		Colletti, et al., "Broad Spectrum Antiprotozoal Agents that Inhibit Histone Deacetylase: Structure-Activity Relationships of Apicidin. Part 1", Bioorganic & Medicinal Chemistry Letters, Vol. 11, pp. 107-111, 2001.
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		Cress, et al., "Histone Deacetylases, Transcriptional Control, and Cancer", J. of Cellular Physiol., Vol. 184, pp. 1-16, 2000.
		Egawa, et al., "Identification of Active Substances from Streptomyces Culture Fluids Using p53-Independent Expression of p21/WAF1/Cip1 Gene and Their Mode of Action", Biol. Pharm. Bull. Vol. 21, Issue 9, pp. 899-904, 1998.
		Furumai, et al., "FK228 (Depsipeptide) as a Natural Prodrug That Inhibits Class I Histone Deacetylases", Cancer Research, Vol. 62, pp. 4916-4921, 2002.
		Galarneau, et al., "β-lactamase protein fragment complementation assays as in vivo and in vitro sensors of protein-protein interactions", Nature Biotechnology, pp. 319-622, 2002.
		GenBank Accession No. AF497972
		GenBank Accession No. U24170
		GenBank Accession No. Z85996
		Grozinger, et al., "Deacetylase Enzymes: Biological Functions and the Use of Small-Molecule Inhibitors", Chemistry & Biology, Vol. 9, pp. 3-16, 2002.
		Han, et al., "Activation of p21WAF1/Cip1 Transcription through Sp1 Sites by Histone Deacetylase Inhibitor Apicidin", J. Biol. Chem., Vol. 276, pp. 42084-42090, 2001.

Examiner
SignatureDate
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			COMPLETE IF KNOWN		
			Application Number		
			Filing Date		
			First Named Inventor		
			Group Art Unit		
			Examiner Name		
Sheet	3	of	4	Attorney Docket Number	
				ITR0053YP	

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Huang, et al., "Activation of the p21WAF1/CIP1 promoter independent of p53 by the histone deacetylase inhibitor suberoylanilide hydroxyamic acid (SAHA) through the Sp1 sites", Oncogene, Vol 19, pp. 5712-5712, 2000.
		Johnstone, et al., "Histone-Deacetylase Inhibitors: Novel Drugs For The Treatment of Cancer", Nature Reviews/ Drug Discovery, Vol. 1, pp. 287-299, 2002.
		Ju, et al., "Histone Deacetylase Inhibitors Activate p21WAF1 Expression via ATM", Cancer Research, Vol. 63, pp. 2891-2897, 2003.
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		Marks, et al., "Histone Deacetylases and Cancer: Causes and Therapies", Nature Reviews/Cancer, Vol. 1, pp. 194-202, 2001.
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		Meinke, et al., "Synthesis of side chain modified apicidin derivatives: potent mechanism-based histone deacetylase inhibitors", Tetrahedron Letters, Vol. 41, pp. 7831-7835, 2000.
		Nakano, et al., "Butyrate Activates the WAF1/Cip1 Gene Promoter through Sp1 Sites in a p53-negative Human Colon Cancer Cell Line*", J. of Biol. Chem., Vol. 272, No. 35, pp. 22199-22206, 1997.
		Nare, et al., "Development of a Scintillation Proximity Assay for Histone Deacetylase Using a Biotinylated Peptide Derived from Histone-H4", Analytical Biochemistry, Vol. 267, pp. 390-396, 1999.
		Perez, et al., "Discovery and SAR of NVP-LAQ824, a novel histone deacetylase inhibitor with in vitro and in vivo antitumor activity", Proc. Am. Assoc. Cancer Res., Vol. 43, Vol. 740, #3671, 2002.
		Richon, et al., "Histone deacetylase inhibitor selectively induces p21WAF1 expression and gene-associated histone acetylation", PNAS, Vol. 97, No. 18, pp. 10014-10019, 2000.
		Sambucetti, et al., "Histone Deacetylase Inhibition Selectively Alters the Activity and Expression of Cell Cycle Proteins Leading to Specific Chromatin Acetylation and Antiproliferative Effects", J. of Biol. Chem., Vol. 274, No. 49, pp. 34940-34947, 1999.
		Sowa, et al., "Histone Deacetylase Inhibitor Activates the WAF1/Cip1 Gene Promoter through the SP1 Sites", Biochem. and Biophys. Res. Comm., Vol. 241, pp. 142-150, 1997.
		Sowa, et al., "Sp3, but not Sp1 Mediates the Transcriptional Activation of the P21/WAF1,Cip1 Gene Promoter by Histone Deacetylase Inhibitor", Cancer Research, Vol. 59, pp. 4266-4270, 1999.

Examiner Signature	Date Considered
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